# Indian Institute of Science

**Bangalore - 560 012.**

## Standard Operating Procedures (SOP) for Institutional Human Ethics Committee (version #1 1/8/2010)

## 1. Objective

The objective of this SOP is to put in place an effective and consistent ethical review mechanism for health and biomedical research for all proposals submitted by the faculty and students of the institute as prescribed by the Ethical guidelines for biomedical research on human participants of ICMR (2006).

## 2. Role of IHEC

IHEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects/participants. The IHEC will take care that all the cardinal principles of research ethics vizAutonomy, Beneficence, Non - maleficence and Justice are taken care of in planning,
conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc.
The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHECs will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

## 3. Composition of IHEC

IHECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IHEC. The number of persons in an ethical committee will be around 8-10 members.
The Chairperson of the Committee should be from outside the Institute
and not head of the Institute to maintain the independence of the Committee. The Member Secretary will be a faculty member from the Institute to conduct the business of the Committee. Other members will be a mix of medical / non-medical,

scientific and non-scientific persons including lay public to reflect different viewpoints. The composition will be as follows :-

1. Chairperson
2. 1-2 basic medical scientists.
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee.

The members will be appointed by the Director of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

IHEC should be constituted in the following pattern :

i) A Chairperson
ii) A Deputy Chairman if need be,
iii) A Member Secretary,
iv) 5 – 7 members from different Departments / Specialties / disciplines or areas etc.

## 4. Authority under which IHEC is constituted:

The Director of IISc constitutes the IHEC.

## 5. Membership requirements:

a. The duration of appointment will be initially for a period of 3 years
b. At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced by a defined procedure.
c. A member can be replaced in the event of death or long-term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons to do so.
e. All members should maintain absolute confidentiality of all discussions during the meeting.
f. Conflict of interest should be declared by members of the IHEC

## 6. Quorum requirements:

The minimum of 5 members + Chairperson are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. This quorum must include at least one non-scientific member that may either be a lawyer, philosopher or a lay person from the community.

## 7. Offices

The Chairperson will conduct all meetings of the IHEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

## 8. Independent consultants

IHEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IHEC .

## 9. Application Procedures:

a. All proposals should be submitted in the prescribed application form.
b. All relevant documents should be enclosed with application form.
c. A soft copy of the proposal along with the application in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators must be sent to the member secretary.
d. The date of meeting will be intimated to the researcher to be present for clarification.
e. The decision will be communicated in writing. If revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

## 10. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents :
1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
Forwarded by the Head of the Institution /Head of the Department. (should be there)4. Protocol of the proposed research
5. List of Ethical issues in the study and plans to address these issues.

6. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances required.
11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance
13. An agreement to report all Serious Adverse events(SAEs)
14.Statement of Conflict of interests,if any
15.An agreement to comply with all national and international guidelines

16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable;
18.All significant previous decisions(e.g.,
those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
18. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
19. Any other information relevant to the study

## 11. Review procedures:

a. The meeting of the IHEC should be held on scheduled intervals of about 3 months
b. The proposals will be sent to members at least 2 weeks in advance.
c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
d. Researchers will be invited to offer clarifications if need be.
e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
f. The decisions will be minuted and Chairperson's approval taken in writing.

## 12. Element of review

a. Scientific design and conduct of the study.
b. Approval of appropriate scientific review committees.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

f. Management of research related injuries, adverse events.
g. Compensation provisions.
h. Justification for placebo in control arm, if any.
i. Availability of products after the study, if applicable.
j. Patient information sheet and informed consent form in local language.
k. Protection of privacy and confidentiality.
l. Involvement of the community, wherever necessary.
m. Plans for data analysis and reporting
n. Adherence to all regulatory requirements and applicable guidelines
o. Competence of investigators, research and supporting staff
p. Facilities and infrastructure of study sites
q. Criteria for withdrawal of patients, suspending or terminating the study

## 13. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified. To expedite review a sub-committee consisting of the member secretary, a non-scientific and a scientific member maybe constituted under the Deputy chairman to review the proposal and approved by the chairperson .

## 14. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.
b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
c. Decisions will be made only in meetings where quorum is complete.
d. Only members can make the decision. The expert consultants will only offer their opinions.
e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
g. Modified proposals may be reviewed by an expedited review through identified members.
h. Procedures for appeal by the researchers should be clearly defined.

## 15. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing.
b. Suggestions for modifications, if any, should be sent by IHEC.
c. Reasons for rejection should be informed to the researchers.
d. The schedule / plan of ongoing review by the IHEC should be communicated to the

PI.

## 16. Follow up procedures

a. Reports should be submitted at annually for review.
b. Final report should be submitted at the end of study.
c. All SAEs and the interventions undertaken should be intimated.
d. Protocol deviation, if any, should be informed with adequate justifications.
e. Any amendment to the protocol should be resubmitted for renewed approval.
f. Any new information related to the study should be communicated.
g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
h. Change of investigators / sites should be informed.

## 17. Record keeping and Archiving

a. Curriculum Vitae (CV) of all members of IHEC.
b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
c. Minutes of all meetings duly signed by the Chairperson.
d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
e. Copy of all correspondence with members, researchers and other regulatory bodies.
f. Final report of the approved projects.
g. All documents should be archived for prescribed period.

## 18. Updating IHEC members

a. All relevant new guidelines should be brought to the attention of the members.
b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Certificate of participation should be kept in record.